UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,906	12/19/2001	Kyoko Kojima	HITA.0135	8851

38327 7590 06/17/2004

REED SMITH LLP
3110 FAIRVIEW PARK DRIVE, SUITE 1400
FALLS CHURCH, VA 22042

EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,906	KOJIMA ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-15 and 18* is/are rejected.

7)☒ Claim(s) *3,4,16 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status

1. This application was withdrawn from issue due to prior art. Since the current action was not necessitated by Applicant's amendment or other action, this action will be non-final.

Claims 1-18 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 2, 5, 6, 8-10, 14, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Henco et al (U.S. Patent 5,057,426).

Henco teaches a method for isolating and purifying nucleic acids (see abstract), which comprises:

(a) providing a mixed solution containing the nucleic acids, salts, and at least one organic solvent (see columns 13 and 14, example 7, where the viral DNA is mixed with salts such as NaCl and organic solvents such as 1% Triton (see line 67);

(b) adsorbing the nucleic acids on an adsorption support (see column 14, line 1, where the DNA is adsorbed onto the porous matrix);

(c) washing the support adsorbed with the nucleic acids with a washing buffer (see column 14, line 2, which teaches washing);

(d) desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids (see column 14, lines 4-5, which teaches elution),

wherein said organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone (See column 13, line 67, where triton is used. Triton is a compound which comprises 2 to 10 carbon atoms and is a aliphatic ether as shown by the attached page 1031 of the 1996 Sigma catalog.

With regard to claim 2, Triton inherently comprises a propylene glycol diethyl ether (see Sigma catalog, page 1031).

With regard to claim 5, Triton is an aliphatic ether (see Sigma catalog, page 1031).

With regard to claims 6, 8, 9 and 10, Triton is present in 1% by volume (see column 13, line 67).

With regard to claims 14, 15 and 18, Henco teaches combining the reagents to use for nucleic acid purification (see columns 11-14).

4. Claims 1, 2, 5-9, 11, 12, 14, 15 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Colpan et al (U.S. Patent 6,383,393).

Colpan teaches a method for isolating and purifying nucleic acids (see abstract), which comprises:

(a) providing a mixed solution containing the nucleic acids, salts, and at least one organic solvent (see columns 9, example 7, where the DNA from blood is mixed with salts such as GuHCl and organic solvents such as 5%-100% Triton (see line 17);

(b) adsorbing the nucleic acids on an adsorption support (see column 9, lines 30-35, where the DNA is adsorbed onto the porous matrix);

(c) washing the support adsorbed with the nucleic acids with a washing buffer (see column 9, lines 33-37, which teaches washing);

(d) desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids (see column 9, lines 40-42, which teaches elution),

wherein said organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone (See column 9, line 17, where Triton is used. Triton is a compound which comprises 2 to 10 carbon atoms and is a aliphatic ether as shown by the attached page 1031 of the 1996 Sigma catalog).

With regard to claim 2, Triton inherently comprises a propylene glycol diethyl ether (see Sigma catalog, page 1031).

With regard to claim 5, Triton is an aliphatic ether (see Sigma catalog, page 1031).

With regard to claims 6-9, Triton is present at least 5% by volume (see column 9, line 17).

With regard to claims 11 and 12, Colpan teaches the use of a column (see column 7) and moving the solution with pressure (see column 9, line 32) or sucking forces (see column 7, line 50).

With regard to claims 14, 15 and 18, Colpan teaches combining the reagents to use for nucleic acid purification (see columns 8-11, especially indication that subject matter is automatable).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 5-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent 6,383,393) in view of Igarishi et al (US 2001/0018219).

Colpan teaches a method for isolating and purifying nucleic acids (see abstract), which comprises:

(a) providing a mixed solution containing the nucleic acids, salts, and at least one organic solvent (see columns 9, example 7, where the DNA from blood is mixed with salts such as GuHCl and organic solvents such as 5%-100% Triton (see line 17);

(b) adsorbing the nucleic acids on an adsorption support (see column 9, lines 30-35, where the DNA is adsorbed onto the porous matrix);

(c) washing the support adsorbed with the nucleic acids with a washing buffer (see column 9, lines 33-37, which teaches washing);

(d) desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids (see column 9, lines 40-42, which teaches elution),

wherein said organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone (See column 9, line 17, where Triton is used. Triton is a compound which comprises 2 to 10 carbon atoms and is a aliphatic ether as shown by the attached page 1031 of the 1996 Sigma catalog).

With regard to claim 2, Triton inherently comprises a propylene glycol diethyl ether (see Sigma catalog, page 1031).

With regard to claim 5, Triton is an aliphatic ether (see Sigma catalog, page 1031).

With regard to claims 6-9, Triton is present at least 5% by volume (see column 9, line 17).

With regard to claims 11 and 12, Colpan teaches the use of a column (see column 7) and moving the solution with pressure (see column 9, line 32) or sucking forces (see column 7, line 50).

With regard to claims 14, 15 and 18, Colpan teaches combining the reagents to use for nucleic acid purification (see columns 8-11, especially indication that subject matter is automatable).

Colpan does not expressly teach repeatedly passing the solution to enhance absorption efficiency.

Igarishi teaches repeating absorption, binding, and washing on the identical stationary phase and finally eluting nucleic acid (see paragraph 59).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the purification method of Colpan by repeating the absorption step since Igarishi states "By repeating absorption, binding, and washing on the identical stationary phase and finally eluting nucleic components from said stationary phase, the method of the present invention can recover nucleic components without reducing the concentrations of nucleic acids and consequently, this method

enables detection of target nucleic acids (see paragraph 40)." Thus an ordinary practitioner interested in collecting the maximum amount of nucleic acid would have been motivated to repeat the absorption step in order to maximize recovery with reducing concentration of desired nucleic acids as taught by Igarishi.

With regard to the specific concentrations of reagents, an ordinary practitioner would have recognized that the results optimizable variables of product concentration could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific concentrations was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Allowable Subject Matter

8. Claims 3, 4, 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: Claims 3, 4, 16 and 17 are drawn to methods in which one of five compounds, propylene glycol monomethyl ether acetate, ethyl lactate, hydroxyacetone, acetone or methyl ethyl ketone were used as the organic solvent. None of the cited prior art

showed the use of any of these compounds in the nucleic acid purification assays. In the absence of a teaching of one of these compounds, they are novel and unobvious over the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637